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FORM 4-1 Application Transmittal

Attorney's Docket No. P-3875 CON PATENT *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): Cornelius Borst
Hendricus J.M. Beck
Paul F. Gründeman
Erij W.L. Jansen

WARNING: Patent must be applied for in the name(s) of all of the actual inventor(s). 37 CFR 1.41(a) and 1.53(b) .

For (title): METHOD AND APPARATUS FOR TEMPORARILY IMMOBILIZING A LOCAL AREA OF TISSUE

1. Type of Application

This new application is for a(n)

(check one applicable item below)

[X] Original (nonprovisional)

[ ] Design

[ ] Plant

WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4) , unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

WARNING: Do not use this transmittal for the filing of a provisional application.

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

[ ]Divisional.

[X]Continuation.

[ ]Continuation-in-part (C-I-P).

2. Benefit of Prior U.S. Application(s)

(35 U.S.C. 119(e), 120, or 121)

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c) , the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c) . (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b) .) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

WARNING: When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional

application must be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3) .

[X]The new application being transmitted claims the benefit of prior U.S. application(s) and enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed That Are Required for Filing Date under 37 CFR 1.53(b)(Regular) or 37 CFR 1.153 (Design) Application ___

Pages of specification	24
Pages of claims	8
Pages of Abstract	2
Sheets of drawing	11

[ ]formal

[X]informal

WARNING: DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84 . Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: ``Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page." 37 C.F.R. 1.84(c)).

(complete the following, if applicable)

[ ]The enclosed drawing(s) are photograph(s), and there is also attached a ``PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. 1.84(b).

4. Additional papers enclosed

[X]Preliminary Amendment

[X]Information Disclosure Statement (37 CFR 1.98)

[X]Form PTO-1449

[ ]Citations

[ ]Declaration of Biological Deposit

[ ]Submission of ``Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.

[ ]Authorization of Attorney(s) to Accept and Follow Instructions from Representative

[ ]Special Comments

[ ]Other

5. Declaration or oath

[X]Enclosed (unsigned)

Executed by

(check all applicable boxes)

[ ]inventor(s).

[ ]legal representative of inventor(s).
37 CFR 1.42 or 1.43 .

[ ]joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

[ ]This is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached.

See item 13 below for fee.

[ ]Not Enclosed.

WARNING: Where the filing is a completion in the U.S. of an International Application, but where a declaration is not available, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S.APPLICATION CLAIMED.

[ ]Application is made by a person authorized under 37 CFR 1.41(c) on behalf of all the above named inventor(s)

(The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently).

NOTE: It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b) .

[ ]Showing that the filing is authorized.

(not required unless called into question. 37 CFR 1.41(d))

6. Inventorship Statement

WARNING: If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

[ ]The same.

or

[X]Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,

[ ]is submitted.

[ ]will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of $130.00 required by 37 CFR 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 CFR 1.52(d) .

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b) .

[X]English

[ ]Non-English

[ ]The attached translation is a verified translation. 37 CFR 1.52(d) .

8. Assignment

[X]An assignment of the invention to MEDTRONIC, INC.

[ ]is attached. A separate [ ] ``COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or [ ] FORM PTO 1595 is also attached.

[X]will follow.

NOTE: ``If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: A newly executed ``CERTIFICATE UNDER 37 CFR 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64. 9. Certified Copy

Certified copy(ies) of application(s)

country appln. no. filed

country appln. no. filed

country appln. no. filed

from which priority is claimed

[ ]is (are) attached.

[ ]will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63 .

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 CFR 1.16)

A. [X]Regular application

CLAIMS AS FILED

	No. of Claims Filed		Claims Included in Base Fee		No. of Extra Claims	Rate	Fee
Total Claims (37 CFR 1.16--20 (c))	13	-	20	=		x 22	$
Independent Claims (37 CFR 1.16--3 (b))	3	-	3	=		x 78	$
Multiple Dependent Claims, if any (37 CFR 1.16 (d))		-	0	=		x 230	$
Basic Filing Fee (37 CFR 1.16 (a))							$ 770
						TOTAL	$ 770

[X]Amendment canceling extra claims enclosed.

[ ]Amendment deleting multiple-dependencies enclosed.

[ ]Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims canceled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d) .

Filing Fee Calculation **$ 770.00**

B. [ ]Design application ($310.00--37 CFR 1.16(f))

Filing Fee Calculation $_____

C. [ ]Plant application ($510.00--37 CFR 1.16(g))

Filing fee calculation $_____

11. Small Entity Statement(s)

[ ]Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is (are) attached.

WARNING: ``Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. A nonprovisional application claiming benefit under 35 U.S.C. 119(e), 120, 121 or 365(c) of a prior application may rely on a verified statement filed in the prior application if the nonprovisional application includes a reference to a verified statement in the prior application or includes a copy of the verified statement filed in the prior application if status as a small entity is still proper and desired." 37 C.F.R. § 1.28(a).

(complete the following, if applicable)

[ ]Status as a small entity was claimed in prior application

_____ / _____, filed on _____, from which benefit is being claimed for this application under:

35 U.S.C-
[ ] 119(e),
[ ] 120,
[ ] 121,
[ ] 365(c),

and which status as a small entity is still proper and desired.

[ ] A copy of the verified statement in the prior application is included.

Filing Fee Calculation (50% of A, B or C above) $_____

NOTE: Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under § 1.136. 37 CFR 1.28(a) .

12. Request for International-Type Search

(37 CFR 1.104(d)) (complete, if applicable)

[ ]Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

[ ]Not Enclosed

[ ]No filing fee is to be paid at this time.

(This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

[X] Enclosed

[X] Basic filing fee **$ 770.00**

[ ] Recording assignment
($40.00; 37 CFR 1.21(h)) $ _____

(See attached ``COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION".)

[ ] Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached.
($130.00; 37 CFR 1.47 and 1.17(h)) $ _____

[ ] For processing an application with a specification in a non-English language. ($130.00; 37 CFR 1-.52(d) and 1.17(k))
$ _____

[ ] Processing and retention fee
($130.00; 37 CFR 1.53(d) and 1.21(l)) $ _____

[ ] Fee for international-type search report
($40.00; 37 CFR 1.21(e)) $ _____

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78 , indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of § 1.21(l) must be paid, within 1 year from notification under § 53(d).

Total fees enclosed **$770.00**

14. Method of Payment of Fees

[ ]Check in the amount of $_____

[X]Charge Account No. 13-2546 in the amount of **$ 770.00**. A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b) .

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

[X]The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 13-2546:

[X]37 CFR 1.16(a), (f) or (g) (filing fees)

[X]37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims canceled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

[X]37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

[X]37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: ``Submission of the appropriate extension fee under 37 C.F.R. 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

[ ]37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b) .

NOTE: 37 CFR 1.28(b) requires ``Notification of any change in loss of entitlement to small entity status must be filed in the application ... prior to paying, or at the time of paying, ... issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as ``other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

[X]Credit Account No. 13-2546.

[ ]Refund

Michael J. Jaro
Reg. No. 34,472
MEDTRONIC, INC.
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432
(612) 574-3279 (voicemail)

[X]Incorporation by reference of added pages

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

[X] Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added 9

[X] Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added 10

[ ] Plus ``Assignment Cover Letter Accompanying New Application"

Number of pages added _____

[ ] Statement Where No Further Pages Added

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item.)

[X] This transmittal ends with this page.

ADDED PAGE(S) FOR SPECIAL COMMENTS FOR NEW APPLICATION TRANSMITTAL

Added page _____

(Added Page(s) for Special Comments for New Application Transmittal

[4-1])

* * * * * * * * * * * * * * * *

End of New Application Transmittal

FORM 4-1.1 Added Pages For Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Attorney's Docket No. P-3875 CON PATENT

TITLE:METHOD AND APPARATUS FOR TEMPORARILY IMMOBILIZING A LOCAL AREA OF TISSUE

INVENTORS: Cornelius Borst
Hendricus J.M. Beck
Paul F. Gründeman
Erik W.L. Jansen

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S.APPLICATION(S) CLAIMED

NOTE: ``In order for an application to claim the benefit of a prior filed copending national application, the prior application must name as an inventor at least one inventor named in the later filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112 ." 37 CFR 1.78(a) .

NOTE: ``In addition the prior application must be (1) complete as set forth in § 1.51, or (2) entitled to a filing date as set forth in § 1.53(b) and include the basic filing fee set forth in § 1.16; or (3) entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) within the time period set forth in § 1.53(d)." 37 CFR 1.78(a) .

17. Relate Back

WARNING:

If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c) , the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to

under 35 U.S.C. 120, 121 or 365(c) . (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b) .) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(complete the following, if applicable)

[X] Amend the specification by inserting, before the first line, the following sentence:

A. 35 U.S.C. 119(e)

NOTE: ``Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)." 37 C.F.R. § 1.78(a)(4).

[ ]``This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

_____ / _____ "

B. 35 U.S.C. 120, 121 and 365(c)

NOTE: ``Any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior

application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross-references to other related applications may be made when appropriate. (See § 1.14(b))." 37 C.F.R. § 1.78(2).

[X] ``This application is a

[X] continuation

[ ] continuation-in-part

[ ] divisional

of copending application(s)

[X] application number 08/531,363 filed on September 20, 1995"

[ ] International Application _____ filed on

_____ and which designated the U.S."

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

[ ] ``The nonprovisional application designated above, namely application

_____ / _____, filed _____, claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

_____ / _____ "

NOTE: The deadline for entering the national phase in the U.S. for an

international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

``The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (i) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application."

18. Relate Back--35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(ies) as follows:

_____

country appln. no. filed on

The certified copy(ies) has (have)

[ ]been filed on _____, in prior application 0 /_____, which was filed on _____.

[ ]is (are) attached.

WARNING: The certified copy of the priority application that may have been

communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application.

This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).

19. Maintenance of Copendency of Prior Application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 0.G. 27).

A. [ ] Extension of time in prior application

(This item must be completed and the papers filed in the prior application if the period set in the prior application has run.)

[ ]A petition, fee and response extends the term in the pending prior application until _____.

[ ]A copy of the petition filed in prior application is attached.

B. [ ] Conditional Petition for Extension of Time in Prior Application

(complete this item, if previous item not applicable)

[ ] A conditional petition for extension of time is being filed in the pending prior application.

[ ]A copy of the conditional petition filed in the prior application is attached.

20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

NOTE: ``If the continuation, continuation-in-part, or divisional application is filed by less than all the inventors named in the prior application a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation, continuation-in-part, or divisional application." 37 CFR 1.62(a) [emphasis added]. (dealing with the file wrapper continuation situation).

NOTE: ``In the case of a continuation-in-part application which adds and claims additional disclosure by amendment, an oath or declaration as required by § 1.63 must be filed. In those situations where a new oath or declaration is required due to additional subject matter being claimed, additional inventors may be named in the continuing application. In a continuation or divisional application which discloses and claims only subject matter disclosed in a prior application, no additional oath or declaration is required and the application must name as inventors the same or less than all the inventors in the prior application." 37 CFR 1.60(c) (dealing with the continuation situation).

(complete applicable item (a), (b) and/or (c) below)

(a) [ ] This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

[ ]the same.

[ ]less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

(type name(s) of inventor(s) to be deleted)

(b)[X] This application discloses and claims additional disclosure by amendment and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

[ ]the same.

[X]the following additional inventor(s) have been added:

Paul F, Gründeman
Erik W.L. Jansen

(type name(s) of inventor(s) to be added)

(c) The inventorship for all the claims in this application are

[ ]the same.

[X]not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

[ ]is submitted.

[ ]will be submitted.

21. Abandonment of Prior Application

(if applicable)

[ ]Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in-part application is a

proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

WARNING: ``The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b) .

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.

(check the next item, if applicable)

[ ]There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

23. Small Entity

(37 CFR § 1.28(a))

[ ]Applicant has established small entity status by the filing of a verified statement in parent application /_____ on _____ .

[ ]A copy of the verified statement previously filed is included.

WARNING: ``Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. Applications filed as continuations, divisions or continuations-in-part of a parent application must include a reference

to a verified statement filed in the parent application if status as a small entity is still proper and desired." 37 CFR § 1.28(a) .

24. Notification In Parent Application Of This Filing

[ ]A notification of the filing of this

(check one of the following)

[ ]continuation

[ ]continuation-in-part

[ ]divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120 .

* * * * * * * * * * * * * * * *

End Of Form 4-1.1 Added Pages For Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Cornelius Borst et al. Examiner: NOT YET ASSIGNED

Serial No.: NOT YET ASSIGNED Group Art Unit: NOT YET ASSIGNED

Filed : NOT YET ASSIGNED Docket: P-3875CON

Title : METHOD AND APPARATUS FOR TEMPORARILY IMMOBILIZING A LOCAL AREA OF TISSUE

PRELIMINARY AMENDMENT

Commissioner of Patents
and Trademarks
Washington, D.C. 26231

Sir:

Please preliminarliy amend the above identified application as follows:

IN THE CLAIMS

Please cancel claims 1-19 and add the following new claims:

26. (New) A method of performing open or closed chest cardiac surgery comprising:

accessing a surface of the heart;

positioning a first member having a first suction port along a first planar surface on the surface of the heart;

coupling a suction source to the suction port of the first member;

creating a suction with the suction source, the created suction then communicated to the first suction port;

grasping the surface of the heart with the suction in the first suction port; and

fixing the first member to a stationary object.

27. (New) The method of claim 26 wherein the step of accessing a surface of the heart comprises a cutting through an intercostal space.

28. (New) The method of claim 26 wherein the step of accessing a surface of the heart comprises inserting an endoscope and a cutting instrument through the chest wall and cutting through the pericardium with the cutting instrument.

29. (New) The method of claim 26 wherein the step of positioning a first member having a first suction port along a first planar surface on the surface of the heart further comprises the steps of providing a first member having a first semi-circular arm, the first semi-circular arm having the first suction port disposed along a first planar surface of the first semi-circular arm.

30. (New) The method of claim 26 wherein the step of positioning a first member having a first suction port along a first planar surface on the surface of

the heart further comprises the steps of providing a first member having a first semi-circular arm and a second semi-circular arm, the second semi-circular arm disposed opposite the first semi-circular arm wherein a substantially circular are is disposed between the semi-circular arms.

31. (New) The method of claim 26 further comprising the steps of:

positioning a second member having a second suction port along a second planar surface on the surface of the heart;

coupling a suction source to the suction port of the second member;

grasping the surface of the heart with the suction in the second suction port; and

fixing the second member to the stationary object.

32. (New) The method of claim 29 further comprising the steps of moving the first member away from the second member. while maintaining the first member and the second member in grasping contact with the surface of the heart.

REMARKS

Applicants have preliminarliy amended the claims to put them into a condition similar to those of the parent application. Namely, in the parent application the claims

were subject to a restriction requirement, of which applicants elected claims 20-25. Applicants have added additional claims in order to better claim the present invention.

Applicant submits all the claims are now in condition for allowance. Passage of the case to issue is respectfully requested. The Examiner is requested to call the undersigned at (011) 31 43 3566845 or leave a voicemail message at (612) 574-3279 to resolve any issues which may hinder speedy passage of the case to issue.

Respectfully submitted,
CORNELIUS BORST et al.

By their attorneys,

19 Aug 97
Date

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PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

TITLE: METHOD AND APPARATUS FOR TEMPORARILY IMMOBILIZING A LOCAL AREA OF TISSUE

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METHOD AND APPARATUS FOR TEMPORARILY IMMOBILIZING A LOCAL AREA OF TISSUE

FIELD OF THE INVENTION

The present invention generally relates to surgery on body tissues and organs. More specifically, the present invention relates to a method and apparatus for temporarily immobilizing a local area of tissue subject to motion, such as the heart wall, which permits a surgical procedure to be performed on that local area of tissue.

BACKGROUND OF THE INVENTION

Coronary artery disease remains the leading cause of morbidity and mortality in Western societies. Coronary artery disease is manifested in a number of ways. For example, disease of the coronary arteries can lead to insufficient blood flow to various areas of the heart. This can lead to the discomfort of angina and the risk of ischemia. In severe cases, acute blockage of coronary blood flow can result in irreversible damage to the myocardial tissue including myocardial infarction and the risk of death.

A number of approaches have been developed for treating coronary artery disease. In less severe cases, it is often sufficient to merely treat the symptoms, with pharmaceuticals, or treat the underlying causes of the disease, with lifestyle modification. In more severe cases, the coronary blockage can be treated endovascularly or percutaneously using techniques such as balloon angioplasty, atherectomy, laser ablation, stents, and the like.

In cases where these approaches have failed or are likely to fail, it is often necessary to perform a coronary artery bypass graft procedure. This procedure generally consists of the following steps: First, direct access to the heart is achieved. This is usually done by opening the chest by median sternotomy and spreading the left and right rib cage apart; and opening the pericardial sac to achieve direct access to the heart.

Next, a blood vessel or vessels for use in the graft procedure are mobilized from the patient. This usually entails mobilizing either a mammary artery or a saphenous vein, although other graft vessels may also be used.

Next, a heart-lung or cardiopulmonary bypass is performed. This usually entails arterial and venous cannulation, connecting the bloodstream to a heart-lung machine, cooling the body to about 32 degrees Celsius, cross-clamping of the aorta and cardioplegic perfusion of the coronary arteries to arrest

and cool the heart to about 4 degrees Celsius. The arrest or stoppage of the heart is generally required because the constant pumping motion of the beating heart would make surgery upon the heart difficult in some locations and extremely difficult if not impossible in other locations

Once cardiac arrest is achieved, then a graft (or grafts) is attached to the relevant portions of a coronary artery (or arteries) followed by weaning from the cardiopulmonary bypass, restarting the heart and decannulation. Finally the chest is closed.

One area which may create difficulties for the patient and extra expense and time for the procedure involves the cardiopulmonary bypass. In a cardiopulmonary bypass all the patient's blood, which normally returns to the right atrium, is diverted to a system which supplies oxygen to the blood and removes carbon dioxide and returns the blood, at sufficient pressure, into the patient's aorta for further distribution into the body. Generally such a system requires several separate components, including an oxygenator, several pumps, a reservoir, a blood temperature control system, filters as well as flow, pressure and temperature sensors.

Problems may develop during cardiopulmonary bypass due to the reaction blood has to non-endothelially lined surfaces, i.e. surfaces unlike those

of a blood vessel. In particular, exposure of blood to foreign surfaces results in the activation of virtually all the humoral and cellular components of the inflammatory response, as well as some of the slower reacting specific immune responses. Other complications from cardiopulmonary bypass include loss of red blood cells and platelets due to shear stress damage. In addition, cardiopulmonary bypass requires the use of an anticoagulant, such as heparin. This may, in turn, increase the risk of hemorrhage. Finally cardiopulmonary bypass sometimes necessitates giving additional blood to the patient. The additional blood, if from a source other than the patient, may expose the patient to blood born diseases.

Due to the risks incurred during cardiopulmonary bypass, others have attempted to perform a coronary artery bypass graft procedure without cardiac arrest and cardiopulmonary bypass. For example, Trapp and Bisarya in "Placement of Coronary Artery Bypass Graft Without Pump Oxygenator", Annals Thorac. Surg. Vol. 19, No. 1, (Jan. 1975) pgs. 1-9, immobilized the area of the bypass graft by encircling sutures deep enough to incorporate enough muscle to suspend an area of the heart and prevent damage to the coronary artery. More recently Fanning et al. in "Reoperative Coronary Artery Bypass Grafting Without Cardiopulmonary Bypass", Annals Thorac. Surg. Vol. 55, (Feb. 1993) pgs. 486-

489 also reported immobilizing the area of the bypass graft with stabilization sutures.

While these attempts have achieved some success, they generally require enhanced skill of the surgeon to properly create the anastomsis because, even with sutures, the beating heart continues to move in the relevant area more than desired.

SUMMARY OF THE INVENTION

It is thus an object of the present invention to provide a method and apparatus for temporarily immobilizing a local area of tissue, such as an area of a beating heart, without requiring the use of stabilizing sutures.

It is a further object of the present invention to provide a method and apparatus to facilitate performing coronary artery bypass graft surgery on a beating heart.

It is the further object of the present invention to provide a method and apparatus to perform a coronary artery bypass graft without requiring the heart to be arrested or stopped and the patient coupled to a cardiopulmonary bypass machine.

These and other objectives are met by the present invention which comprises a method and apparatus for temporarily immobilizing a local area of tissue. In particular, the present invention provides a method and apparatus for temporarily immobilizing a local area of heart tissue to thereby permit surgery on a coronary vessel in that area without significant deterioration of the pumping function of the beating heart. The local area of heart tissue is immobilized to a degree sufficient to permit minimally invasive or micro-surgery on that area of the heart. The present invention features a suction device to accomplish the immobilization. The suction device is coupled to a source of negative pressure. The suction device has a series of suction ports on one surface. Suction through the device causes suction to be maintained at the ports. The device further is shaped to conform to the surface of the heart. Thus, when the device is placed on the surface of the heart and suction is created, the suction through the ports engages the surface of the heart. The suction device is further fixed or immobilized to a stationary object, such as an operating table or a sternal or rib retractor. Thus, the local area of the heart near the suction device is temporarily fixed or immobilized relative to the stationary object while suction is maintained. In such a fashion, the coronary artery may be immobilized even though the heart itself is still beating so that a bypass graft may be performed. In addition the suction device may be used in either a conventional, open-chest environment or in a minimally-invasive environment, e.g. endoscopic.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other aspects of the present invention will best be appreciated with reference to the detailed description of the invention in conjunction with the accompanying drawings, wherein:

FIG. 1 is a plan view of the device being used to temporarily immobilize a local area of heart tissue in which access to the heart is achieved through a mini-thoractomy.

FIGS. 2a and 2b depict a first type of suction device shown in use in FIG. 1.

FIGS. 3a and 3b depict a second type of suction device shown in use in FIG. 1.

FIG. 4 is a longitudinal sectional view of the suction paddle used in the present invention.

FIG. 5 is a cross-sectional view of the suction paddle used in the present invention taken along the line 5-5 of FIG. 4.

FIG. 6 is a longitudinal sectional view of the suction arm used in the present invention.

FIG. 7 is a plan view of the suction arm used in the present invention.

FIG. 8 is a detailed view of a pair of suction devices being positioned on a heart and spread apart.

FIGS. 9 and 10 show the effect of the spread-apart motion depicted in FIG. 8.

FIG. 11 is an example of the motion in the plane parallel to the surface of the heart of a point on heart tissue during one half respiratory cycle when the heart is unrestrained and also depicting the motion of the same point on heart tissue when the suction devices are used.

FIG. 12 is an enlarged portion of FIG. 11 depicting the motion of the same point on heart tissue when the suction devices are used.

FIG. 13 is an alternate embodiment of the present invention.

FIG. 14 is a plan view of the device being used to temporarily immobilize a local area of heart tissue in which access to the heart is achieved through a median sternotomy.

FIG. 15 is a side view of an alternate embodiment of the present invention, shown placed against the surface of the heart.

FIG. 16 is a bottom view of the alternate embodiment of the present invention device shown in FIG. 15.

FIG. 17 is a side view of a further alternate embodiment of the present invention, shown placed against the surface of the heart.

FIG. 18 is a bottom view of still further alternate embodiment of the present invention.

FIG. 19 is a cross-sectional view of a body showing an alternative method of achieving access to the surface of the heart, and in particular of achieving such access using minimally invasive trocars.

The drawings are not necessarily to scale.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 is a view of the immobilizing device 11 being used to temporarily immobilize an area of heart tissue. In the preferred embodiment, surgical access to the local area of heart tissue is achieved through a mini-

thoracotomy, preferably performed within either the fourth or fifth intercostal space. An incision 10 of approximately 10 centimeters is made into chest cavity between the ribs (seen here in phantom.) The rib cartilage may be temporarily removed and the ribs surrounding the incision slightly spread apart using a retractor (not shown) to provide adequate surgical access to the mammary artery and the heart. As seen, a pair of suction devices 12, 13 are introduced. The first suction device 12 is introduced through a small stab wound 8 in between the ribs approximately 10 cm. below incision 10. This stab wound is made in any acceptable manner. Incidentally, once the surgery has been completed, the stab wound may be used for the thorax drain after the closure of the chest. As discussed below with reference to FIG. 19, the suction device has a covering 180, made from latex rubber, over the distal end when it penetrates the chest wall in order to avoid blood and tissue from entering the suction ports and block suction apertures. Once suction device is introduced, covering 180 is removed and the distal end is positioned onto heart. The second suction device 13 is introduced through incision 10 onto the surface of the heart. As seen, the distal end of each suction device is ultimately positioned in the local area of heart tissue to be immobilized, i.e. on either side of a coronary artery upon which a graft is to be made.

As seen, suction devices 12, 13 are secured using securing devices 14, 15 respectively to a stationary object, such as surgical table 16. Of course other objects besides the surgical table may be used as a stationary object, including the floor, ceiling or even the patient, such as a portion of the skeletal system of the patient, e.g. the sternum. In the preferred embodiment, each securing device 14,15 is a variable friction arm, model no. 244 available from Manfrotto Nord, Inc. of Zona Industriale di Villapaiera, I-32032 Feltre BL, Italy. Each securing device 14, 15 has a series of elbow joints 17 which may be locked in position. Thus the securing device permits the suction device to be locked into any position desired within three-dimensional space. Although not show, each securing device (or each suction device or both) may also be interconnected such that a truss type structure is created and the entire stiffness or rigidity of the immobilizing device 11 is improved.

Suction devices 12, 13 are coupled to a suction source 114 through lines 20, 21. Suction source 114 is preferably the standard suction available in the operating room and coupled to the devices with a two liter buffer flask (not shown) for each device. Suction is provided at a negative pressure of between 200-600 mm Hg with 400 mm Hg preferred. As seen, each suction device has essentially two portions, a paddle 22 and an arm 23. FIGS. 2 and 3 detail suction devices 12 and 13 respectively.

Turning now to FIGS. 2a and 2b, FIG. 2a is a side view of a suction device 12 showing its placement against the outline of a heart. As seen, the distal end of suction device comprises a paddle 22 and arm 23 coupled together by a continuous hinge or neck 71. Paddle 22 has a generally planar surface which conforms generally to the curvature of a heart 1, shown here in outline. In the preferred embodiment, suction arm 23 is coupled to suction paddle 22 such that suction paddle 22 may be rotated or bent to achieve the desired orientation relative to arm 23. This is accomplished by neck 71. Neck 71 is fashioned to be relatively bendable, that is to be bent by hand into the desired orientation, as opposed to paddle 22 and arm 23, which are rigid. In the preferred embodiment suction paddle 22 and suction arm 23 are constructed of stainless steel 316, while neck 71 is constructed of stainless steel 321. Of course other means may be provided to permit paddle 22 to move or rotate relative to arm 23 other than making neck 71 to be malleable by hand, such as a locking hinge as well as a remotely actuable joint, as is well known in the art. See for example, U.S. Patent No. 5,374,277 of Hassler, incorporated herein by reference. A remotely actuable hinge is believed particularly advantageous for a suction device used endoscopically. In an alternate embodiment paddle may be fixed in a rigid orientation relative to arm. As seen, arm 23 has a suction lumen 30 therethrough which communicates with a suction conduit 31 in paddle 22

through neck lumen 72. Suction conduit 31 in paddle 22 further communicates through suction hole 32 (best seen in FIG. 2b) to suction port 33.

FIG. 2b is a view of the bottom of suction device 12. As seen, in the preferred embodiment four suction ports 33 in a row are featured, although the specific or exact number and position used may vary. Each suction port 33 has a suction aperture 32, each of which are preferably located at a position off-center from suction port 33. Suction apertures 32 are positioned off center from suction ports 33 so that if a large upwelling of tissue is caused by the suction (which may occur as a blister or bell-shaped curve) the tissue will not immediately close off the suction by obstructing suction aperture 32, as it would if the aperture were in the center of suction port 33. In addition, each suction aperture 32 has a much smaller diameter as compared to the diameter of suction port 33. This creates a high resistance pathway between suction port 33 and suction conduit 31 which permits the loss of a tissue-to-port seal in one suction port (and thus loss of fixation of the suction port to the tissue) to not also cause a precipitous pressure drop in the remainder of the suction ports. In the preferred embodiment suction aperture 32 has a diameter of 2 mm and suction port 33 has a diameter of 6 mm.

Turning now to FIGS. 3a and 3b, FIG. 3a is a side view of a suction device 13 shown in FIG. 1. As seen, the distal end of suction device 13

comprises paddle 22 and arm 23 coupled together by a continuous hinge or neck 71. Paddle 22 has a generally planar surface which conforms generally to the curvature of a heart 1. In the preferred embodiment, suction arm 23 is coupled to suction paddle 22 such that suction paddle 22 may be rotated or bent along any of the three axes to achieve the desired orientation relative to arm 23. This is accomplished by neck 71. Neck 71 is substantially similar to that discussed in FIG. 2a but for the fact that suction device 13 has suction paddle 22 at an angled orientation to suction arm 23. In the preferred embodiment suction paddle 22 of suction device 13 is perpendicular to suction arm 23, although other angular orientations may be used.

FIG. 3b is a view of the bottom of suction device 13. As seen, in the preferred embodiment suction paddle 22 of suction device 13 is substantially similar to that described in FIG. 2b. In the preferred embodiment suction aperture 32 has a diameter of 2 mm and suction port 33 has a diameter of 6 mm.

FIG. 4 is a longitudinal cross-sectional view of suction paddle 22 used in immobilizing device 11. As seen, paddle 22 has a series of suction ports 33 each of which is connected to suction conduit 31 through a suction aperture 32. Each suction port 33 has generally straight, cylindrical sides. Of course other configurations may be used, such as cone-shaped suction ports, dome-shaped suction ports, etc.

FIG. 5 is a cross-sectional view of the suction paddle 22 taken along the line 5-5 of FIG. 4. As seen, suction port 33 is connected to suction conduit 31 through suction aperture 32. Suction paddle 22 has a canted or slanted surface 36 at the top. Through this type of surface, area 37 may be better accessed for performing surgical procedures.

FIG. 6 is a longitudinal cross-sectional view of suction arm 23. Distal end 71 of suction arm 23 has neck 71 (not shown in this FIG.) fixed thereto. As seen, arm 23 has a suction lumen 30 therethrough which communicates with suction conduit 31 in paddle 22 through neck lumen 72 of neck 71 (shown in phantom in this FIG.). As seen in FIG. 7, which is a plan view of suction arm 23, proximal end 75 has a series of knurled ridges 76 to facilitate coupling a suction line coming from suction source (not shown in this FIG) to suction arm 23.

FIG. 8 is a detailed view of a pair of suction devices 12, 13 being positioned on a heart and spread apart. As seen, paddles 22, 27 of each device generally are placed in the area 34 in which temporary immobilization of the heart tissue is desired. When used for a coronary bypass graft, area 34 typically will have a coronary artery 35 running therethrough. Area 34 is between paddles

22, 27. Once placed about area 34, suction is then created in the suction ports (not shown in this view.) Through the suction, the device then is fixed to or grabs hold of the heart tissue.

Once the suction is created and the paddles are secured to the heart tissue, each of the suction devices are then spread slightly apart as shown by the arrows 40, 41 to the positions shown as 42, 43. The effect of this spreading apart is to cause a tension to be created in the area 34 of the heart tissue between the paddles. The tension causes the area 34 to be further immobilized, and in particular in the Z-direction, i.e. in the direction normal to the plane defined by the surface of the heart. This is represented in FIGS. 9 and 10.

As seen in FIG. 9, the area of heart tissue between the paddles, even with the placement of the paddles, still has some vertical motion, shown here as arrow 50. When paddles 22, 27 are slightly spread apart to cause a tension in that area 34 of tissue between the paddles, as depicted in FIG. 10, then the amount of movement in the area 34 between the paddles 22, 27 due to the tension is further decreased, especially in the Z-direction, i.e. the direction perpendicular to the surface of the heart 1. Once the paddles 22, 27 are thus positioned and secured and the area of the tissue is temporarily immobilized, the coronary artery in that area may be operated upon.

In the preferred embodiment, the anastomosis of the coronary artery may be accomplished through any acceptable end-to-side or side-to-side technique. Of course, other methods of performing the anastomosis may be used, such as those methods which may be performed endoscopically.

FIG. 11 is an example of the motion in the plane parallel to the surface of the heart of a point on heart tissue during one half respiratory cycle when the heart is unrestrained and also depicting the motion of the same point on heart tissue when the suction devices are used. Line 60 is a tracing of the motion of a point of tissue on the cardiac surface. As seen by line 60, a point on the cardiac surface moves approximately 15 mm in each direction. Generally, each loop of movement depicts the motion of the beating heart within one cardiac cycle. Thus, loop 61 occurs due to one cardiac cycle. Loop 62 occurs due to the next cardiac cycle, but the entire heart has shifted in location somewhat due to the inflation or deflation of the lungs associated with respiration. Line 63 shows the motion of the same point of heart tissue when the suction device is placed near the area and the heart wall is immobilized by the present invention. As seen, the present invention functions to minimize heart wall movement in that area to approximately 1 mm in each direction. This is best seen in FIG. 12 which is an enlarged portion of FIG. 11 and in particular line 63. As seen, through the use of the present invention, heart wall movement has

been decreased to only slightly more than 1 mm. Decreased to an amount in the area of the suction devices such that the still-beating heart may be operated upon in that area using an endoscope or any other method of minimally invasive surgery.

FIG. 13 is an alternate embodiment of the present invention. As seen, the embodiment of FIG. 13 comprises a suction sleeve 80 which is coupled to an annular suction head 81 via a ball bearing joint 84. Ball bearing joint 84 may be provided so as to permit remote actuation of the suction head 81 from a position outside the chest. The suction head 81 has a series of suction ports 82 located along a first planar surface. In the embodiment shown the planar surface upon which the suction ports 82 are located is conical in shape, although other types of planar surface may be used, such as frusto-conical for example. The suction head 81 may be constructed such that each half of the device is coupled to a separate suction source. Through such a configuration, if one-half of the suction head 81 were to lose contact with the surface, the other one-half of the suction head 81 could maintain capture. The suction sleeve 80 is used as described above. That is the suction sleeve 80 itself is coupled to a suction source (not shown but the same as suction source 114) and is fixed or immobilized to a stationary point, such as the operating table or a retractor (also not shown.) Suction through the suction source and the suction sleeve 80 then

causes the suction ports 82 to suck upon the heart tissue. Through this configuration, then, the heart tissue in the center of suction sleeve is immobilized. Interruption or opening 83 permits suction head 81 to be fixed to heart tissue while permitting a blood vessel to be grafted. In particular, if a mammary artery has been grafted end-to-side to a coronary artery, then the opening 83 permits the suction head 81 to be removed from around the grafted artery.

FIG. 14 is a view of the device being used to temporarily immobilize a local area of heart tissue using an alternative access procedure to the preferred mini-thoracotomy. In particular heart 1 is exposed with an incision 2 through the patient's sternum and the chest is spread apart by a retractor 3 to provide access to the heart 1. Access to the heart 1 is further effected by retraction of the pericardium 4 in the area of the heart 1 which is to be operated on. As shown pericardial retraction is accomplished through sutures 5.

As seen, the immobilizing device 11 comprises a pair of suction devices 12, 13 and a suction source 114. Suction devices 12, 13 are secured to patient be securing each to retractor 3 through a pair of clamps 19. Of course suction devices 12, 13 may also be secured to the operating table (not shown in this FIG. but using a securing device as described above.) Suction devices are coupled to suction source 114 through lines 20, 21. Suction source 114 is

preferably the standard suction available in the operating room and coupled to the devices with a two liter buffer flask (not shown) for each device. Suction is provided at a negative pressure of between 200-600 mm Hg with 400 mm Hg preferred. As seen, each suction device has essentially two portions, a paddle 22 and an arm 23.

Turning now to FIG. 15 which is a side view of an alternate embodiment of suction device 12 showing its placement against the outline of a heart. As seen, the distal end of suction device comprises a paddle 22 and arm 23. Paddle 22 has a generally planar surface which conforms generally to the curvature of a heart 1, shown here in outline. The paddle 22 is coupled to arm 23 through a pin 24. The pin 24 permits the paddle 22 to be swiveled to the preferred angle relative to arm 23. As seen, arm 23 has a suction lumen 30 therethrough which communicates with a suction conduit 31 in paddle 22. Suction conduit 31, in turn, communicates through suction aperture 32 (best seen in FIG. 4) to suction port 33.

FIG. 16 is a view of the bottom of suction device 12 shown in FIG. 15. As seen, four suction ports 33 in a row are featured, although the specific or exact number and position used may vary.

FIG. 17 is a further alternate embodiment of a suction device 12 showing its placement against the outline of a heart. As seen, suction device 12 is substantially similar to that shown and described in FIG. 2, but for the addition of suture coil 73. Suture coil 73 is a tightly wound spring fixed to the top surface of suction paddle 22. Further temporary stabilization of the coronary anastomosis site may be achieved, if desired, by catching epicardial flaps with light traction sutures. Suture coil 73 permits these and any other sutures to be temporarily fixed in place by wedging the suture between within suture coil 73, as is known in the art.

FIG. 18 is a bottom view of a further alternate embodiment of suction device 12. As seen, suction device 12 is substantially similar to that shown and described in FIG. 2, but for the addition of electrode 174 along a side of suction paddle 22. Electrode 174 is coupled by lead 175 to pulse generator 176. Electrode 174, lead 175 and pulse generator 176 may be provided according to well know methods and materials so as to permit the heart to be paced, cardioverted or defibrillated while suction device 12 is fixed to the surface of the heart.

FIG. 19 is a cross-sectional view of a body showing an alternate method of achieving access to a surface of the heart and using the present invention to immobilize an area of tissue. As seen suction device 12 is

introduced through a first stab wound. As discussed above, suction arm 23 of device 12 is secured by securing device 14 to a stationary object, such as operating table 16. A second suction device may also be introduced through a second stab wound to securely immobilize a local area of tissue. Each suction device has a covering 180, made from latex rubber, over the distal end when it penetrates the chest wall in order to avoid blood and tissue from entering the suction ports and block suction apertures. Two or more additional surgical trocars 78 may be introduced to permit endoscopy and surgical access to heart 1. In addition the left lung 79 may also be partially collapsed so as to provide an unencumbered area in which to manipulate the surgical instruments.

As disclosed, the present invention relates to a method and apparatus for immobilizing tissue. In the preferred embodiment, the invention is used to immobilize heart tissue for a coronary artery bypass graft procedure using either an open or closed chest approach, without the need for a cardiopulmonary bypass. Other surgical techniques, however, which require immobilizing body tissue may also be performed using the present invention, such as surgery on other organs such as the stomach, gall bladder, etc., as well as on other body tissues, such as the eye or the skin, for example. In addition, while the present invention has been described in detail with particular reference to a preferred embodiment and alternate embodiments, it should be understood

variations and modifications can be effected within the scope of the following claims. Such modifications may include substituting elements or components which perform substantially the same function in substantially the same way to achieve substantially the same result for those described herein.

WHAT IS CLAIMED IS

1. A device for temporarily immobilizing an area of tissue comprising:

a suction source;

a member having a lumen, the lumen coupled to a suction port, the suction port positioned along a first planar surface of the member, the lumen coupled to the suction source, wherein suction to the lumen is communicated to the suction port; and

means for fixing the member to a stationary object.

2. The device of claim 1 wherein the member comprises an arm and a paddle, the paddle coupled to the arm by a hinge.

3. The device of claim 2 wherein the hinge comprises a malleable neck, the neck having a proximal end and a distal end, the distal end coupled to the arm, the distal end coupled to the paddle.

4. The device of claim 2 wherein the paddle may be fixed in an angular relationship to the arm by the hinge.

5. The device of claim 1 wherein the member further comprises an arm and a paddle, the paddle coupled to the arm at a first angle.

6. The device of claim 1 wherein the member further comprises an arm and a paddle, the paddle movably coupled to the arm at a first angle.

7. The device of claim 1 wherein the first planar surface of the member is curved.

8. The device of claim 2 wherein the lumen extending through the arm to the paddle, the lumen further extending through the arm to the suction port, the suction port positioned on the paddle.

9. The device of claim 1 wherein the first planar surface is curved.

10. The device of claim 1 wherein the stationary object is an operating table.

11. The device of claim 1 wherein the stationary object is a retractor.

12. A device for immobilizing an area of tissue comprising:

a first member having a suction port along a first plane;

a second member having a suction port along the first plane, the second member positioned apart from the first member such that an immobilized area is defined between;

a securing device to secure the first member and the second member to an immobile object, the securing device coupled to the first member and the second member.

13. The device of claim 12 wherein the first plane is curved.

14. The device of claim 12 wherein the securing device comprises a first variable friction arm having at a first lockable elbow joint and a second first variable friction arm having at a second lockable elbow joint.

15. The device of claim 12 further comprising a first suction source coupled to the first member and communicating with the suction port of the first member and a second suction source coupled to the second member and communicating with the suction port of the second member.

16. A device for immobilizing an area of tissue comprising a member having a suction conduit therein, the suction conduit communicating

with a suction port located along a first plane of the member, the suction conduit communicating with the suction port through a suction aperture, the suction port having a suction port diameter, the suction aperture having suction aperture diameter, the suction port diameter being greater than the suction aperture, the suction conduit coupleable to a suction source.

17. The device of claim 16 wherein the suction port diameter is three times greater than the suction aperture.

18. The device of claim 16 wherein the suction port has generally straight, cylindrical sides.

19. The device of claim 16 wherein the member is secured to a stationary object by a securing device.

20. A method of performing open or closed chest cardiac surgery comprising:

accessing a surface of the heart;

positioning a first member having a first suction port on the surface of the heart;

coupling a suction source to the suction port of the first member;

creating a suction with the suction source, the created suction then communicated to the first suction port;

grasping the surface of the heart with the suction in the first suction port; and

fixing the first member to a stationary object;.

21. The method of claim 20 wherein the step of accessing a surface of the heart comprises a cutting through an intercostal space.

22. The method of claim 20 wherein the step of accessing a surface of the heart comprises inserting an endoscope and a cutting instrument

through the chest wall and cutting through the pericardium with the cutting instrument.

23. The method of claim 20 further comprising the steps of:

positioning a second member having a second suction port on the surface of the heart;

coupling a suction source to the suction port of the second member;

grasping the surface of the heart with the suction in the second suction port; and

fixing the second member to the stationary object.

24. The method of claim 23 further comprising the steps of moving the first member away from the second member. while maintaining the first member and the second member in grasping contact with the surface of the heart.

25. A method of immobilizing an area of tissue comprising:

contacting a first suction port on a first paddle to a planar surface of tissue;

contacting a second suction port on a second paddle to the planar surface of the tissue;

creating a suction in the first suction port to cause the first suction port to grasp the planar surface of the tissue;

creating a suction in the second suction port to cause the second suction port to grasp the planar surface of the tissue;

moving the first paddle away from the second paddle along the planar surface of the tissue;

fixing the first paddle to a stationary object; and

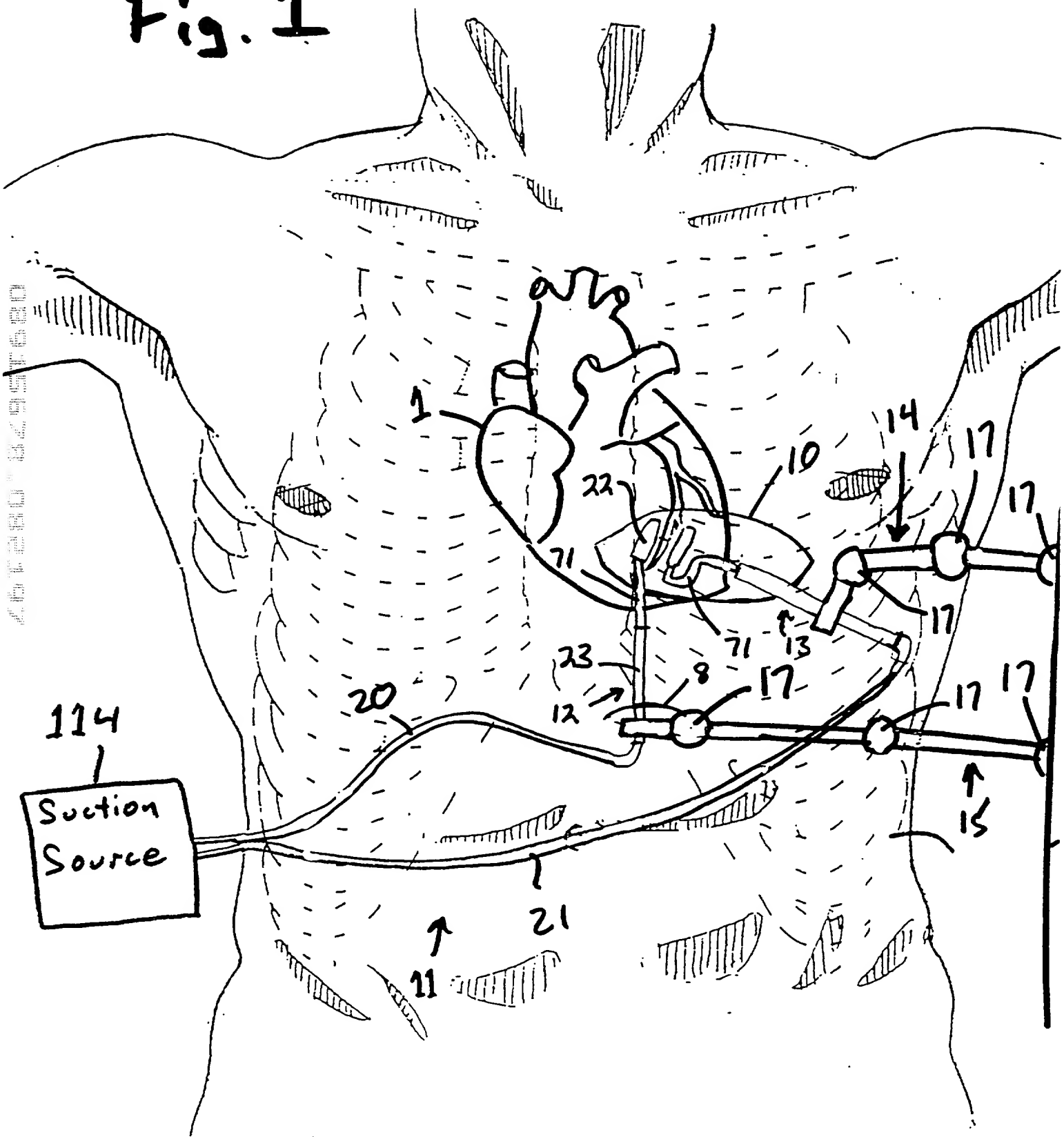
fixing the second paddle to a stationary object.

ABSTRACT

A method and apparatus for temporarily immobilizing a local area of tissue. In particular, the present invention provides a method and apparatus for temporarily immobilizing a local area of heart tissue to thereby permit surgery on a coronary vessel in that area without significant deterioration of the pumping function of the beating heart. The local area of heart tissue is immobilized to a degree sufficient to permit minimally invasive or micro-surgery on that area of the heart. The present invention features a suction device to accomplish the immobilization. The suction device is coupled to a source of negative pressure. The suction device has a series of suction ports on one surface. Suction through the device causes suction to be maintained at the ports. The device further is shaped to conform to the surface of the heart. Thus, when the device is placed on the surface of the heart and suction is created, the suction through the ports engages the surface of the heart. The suction device is further fixed or immobilized to a stationary object, such as an operating table or a sternal or rib retractor. Thus, the local area of the heart near the suction device is temporarily fixed or immobilized relative to the stationary object while suction is maintained. In such a fashion, the coronary artery may be immobilized even though the heart itself is still beating so that a bypass graft may be performed. In addition the

suction device may be used in either a conventional, open-chest environment or in a minimally-invasive environment, e.g. endoscopic.

Fig. 1


1
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Suction Source
15
21
11

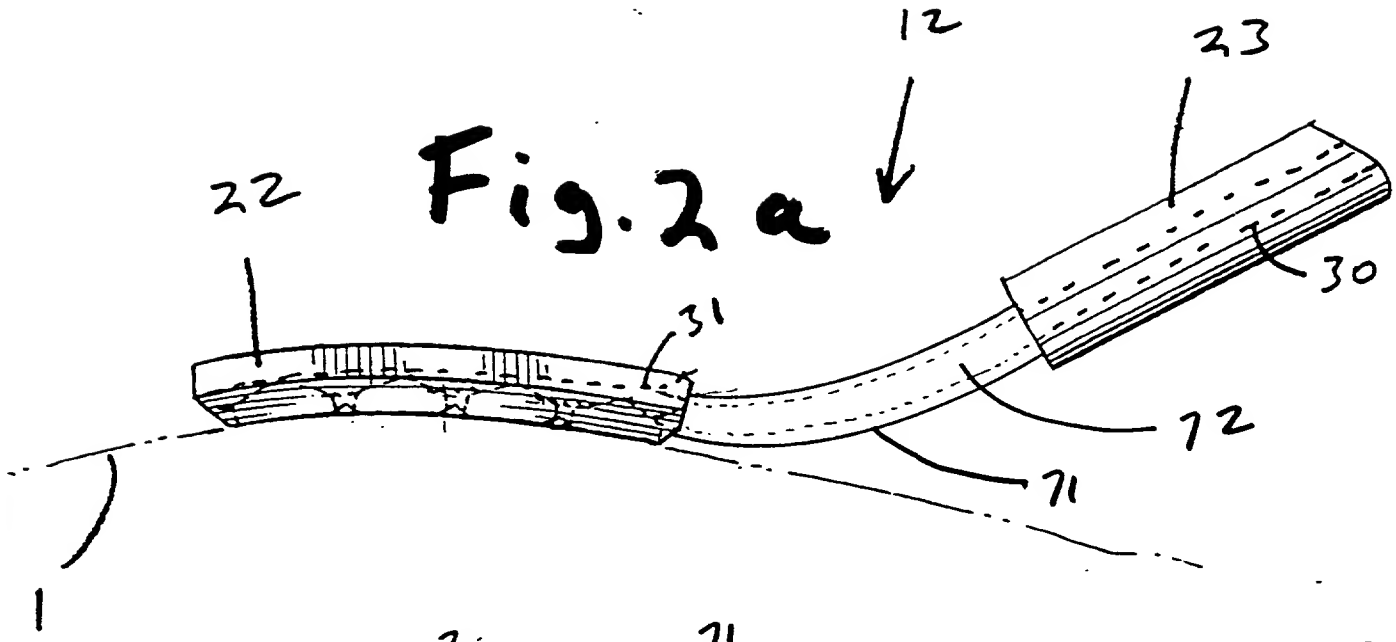


Fig. 2a

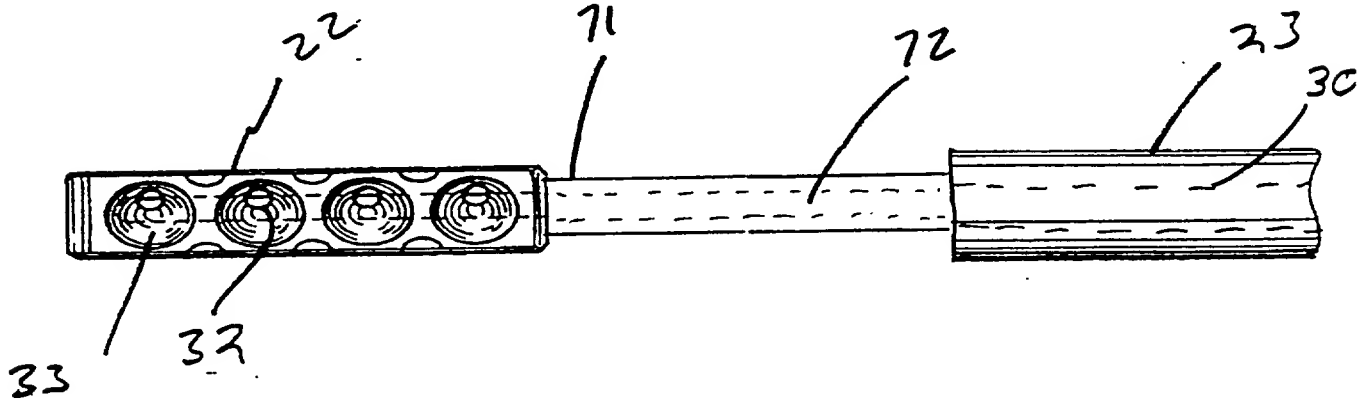


Fig. 2b

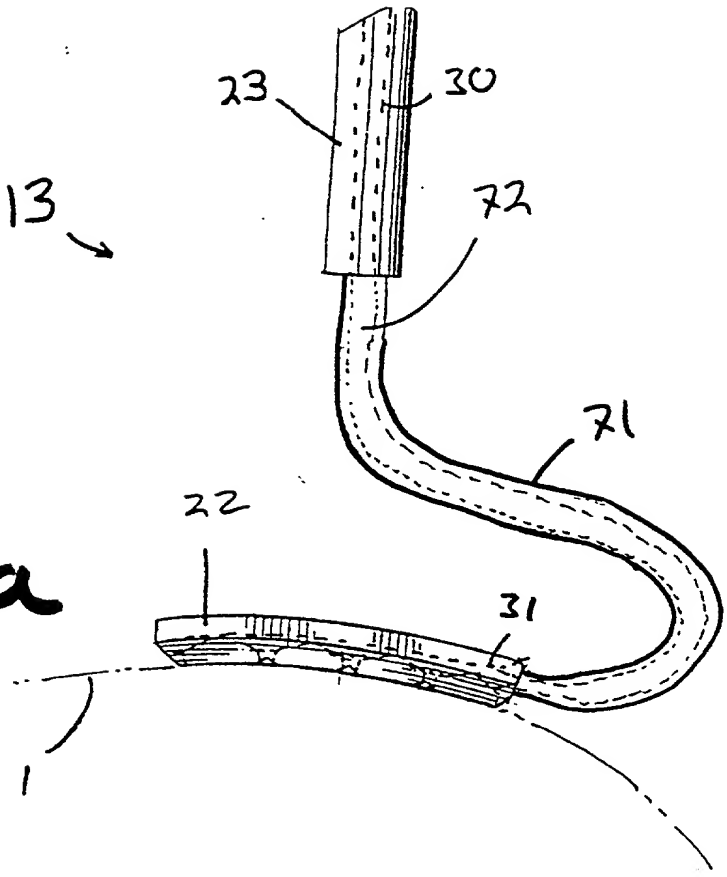


Fig. 3 a

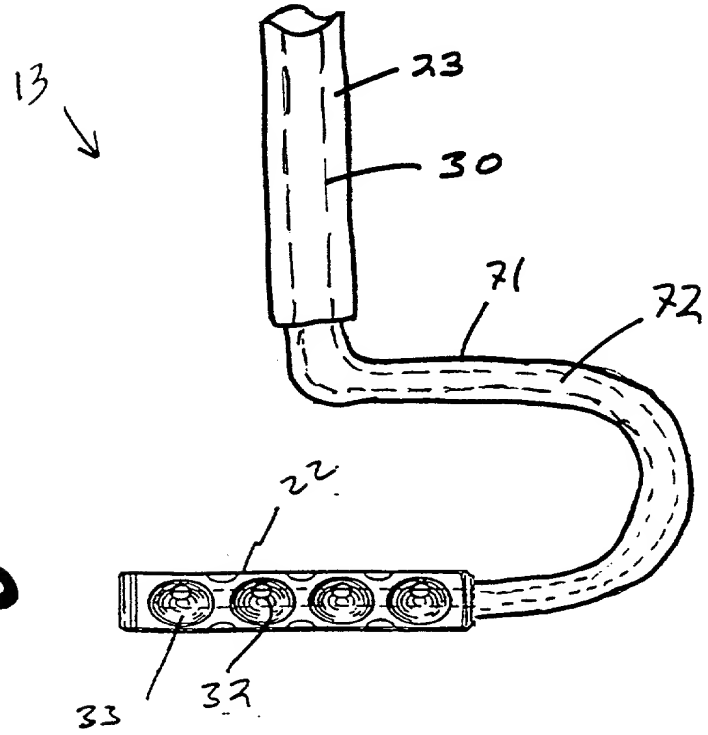


Fig. 3 b

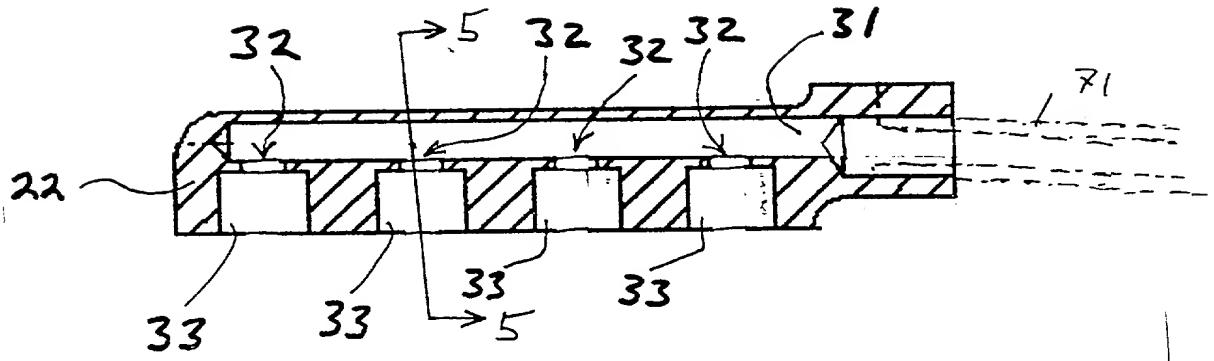


Fig. 4

Fig. 5

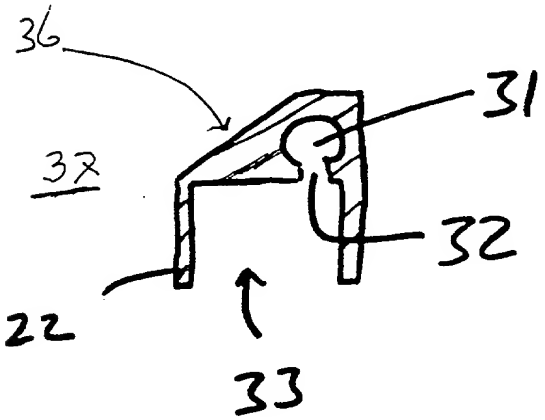
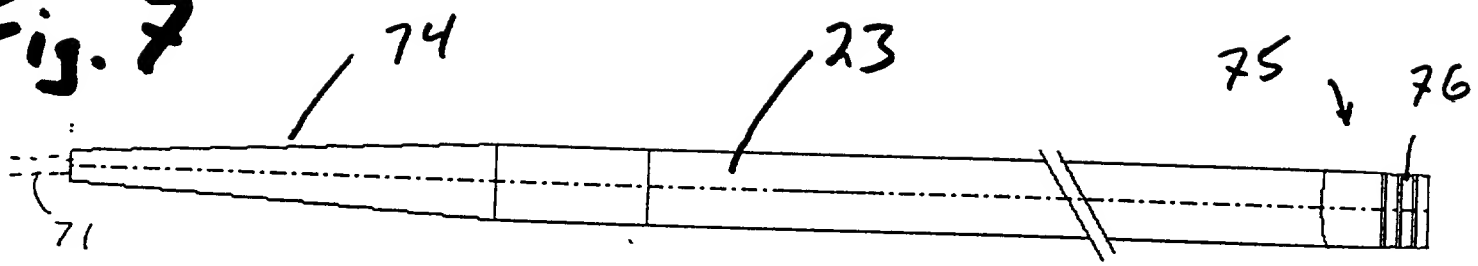


Fig. 7



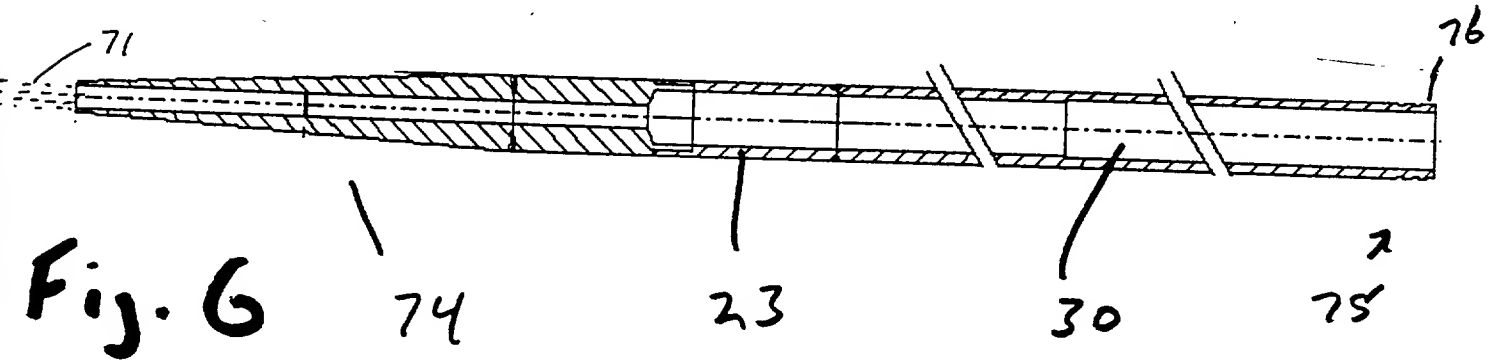


Fig. 6

Fig. 8

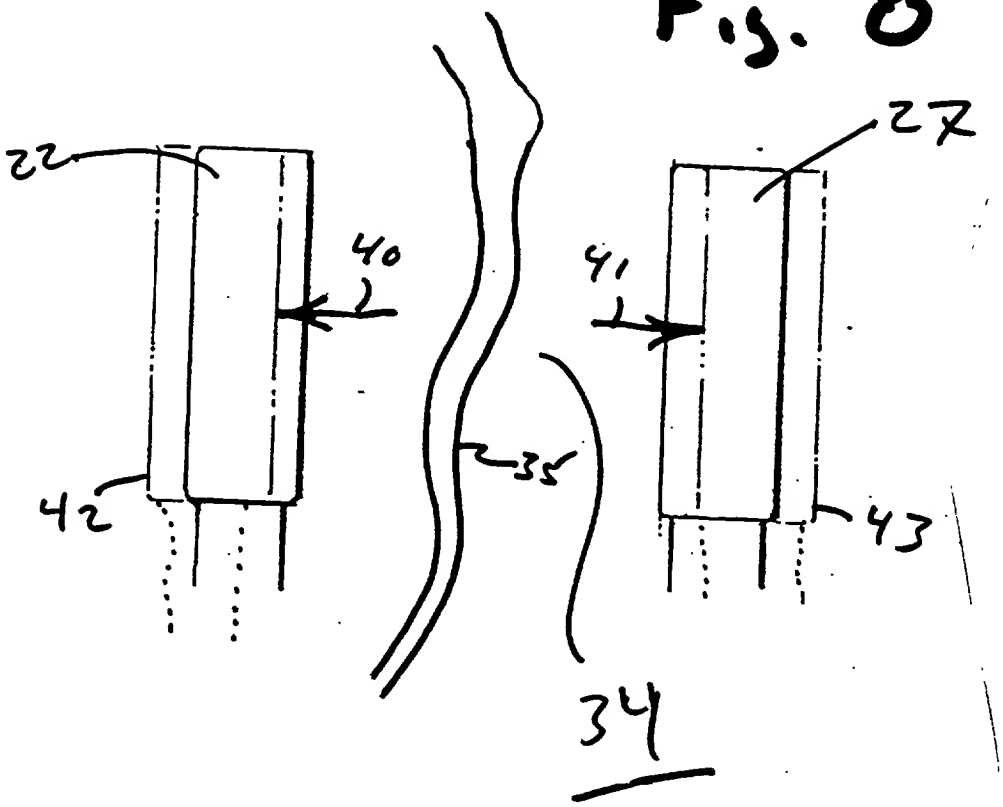


Fig. 9

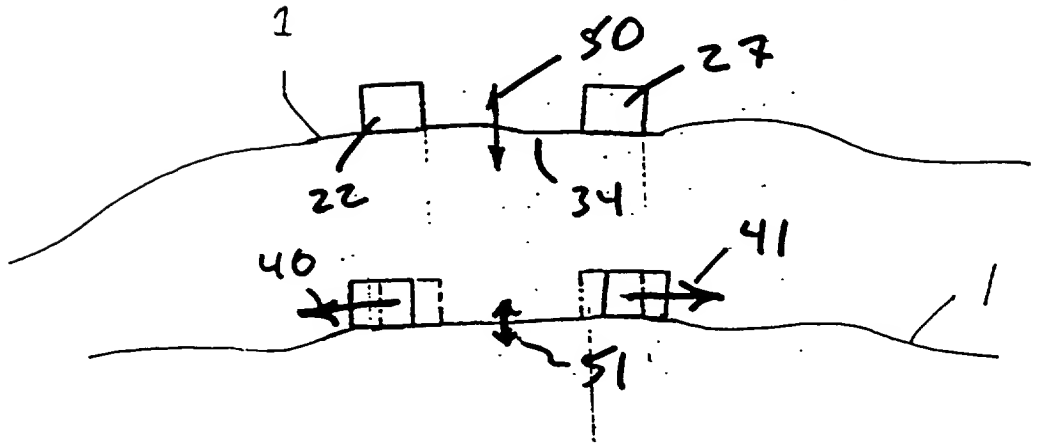


Fig. 10

Fig. 11

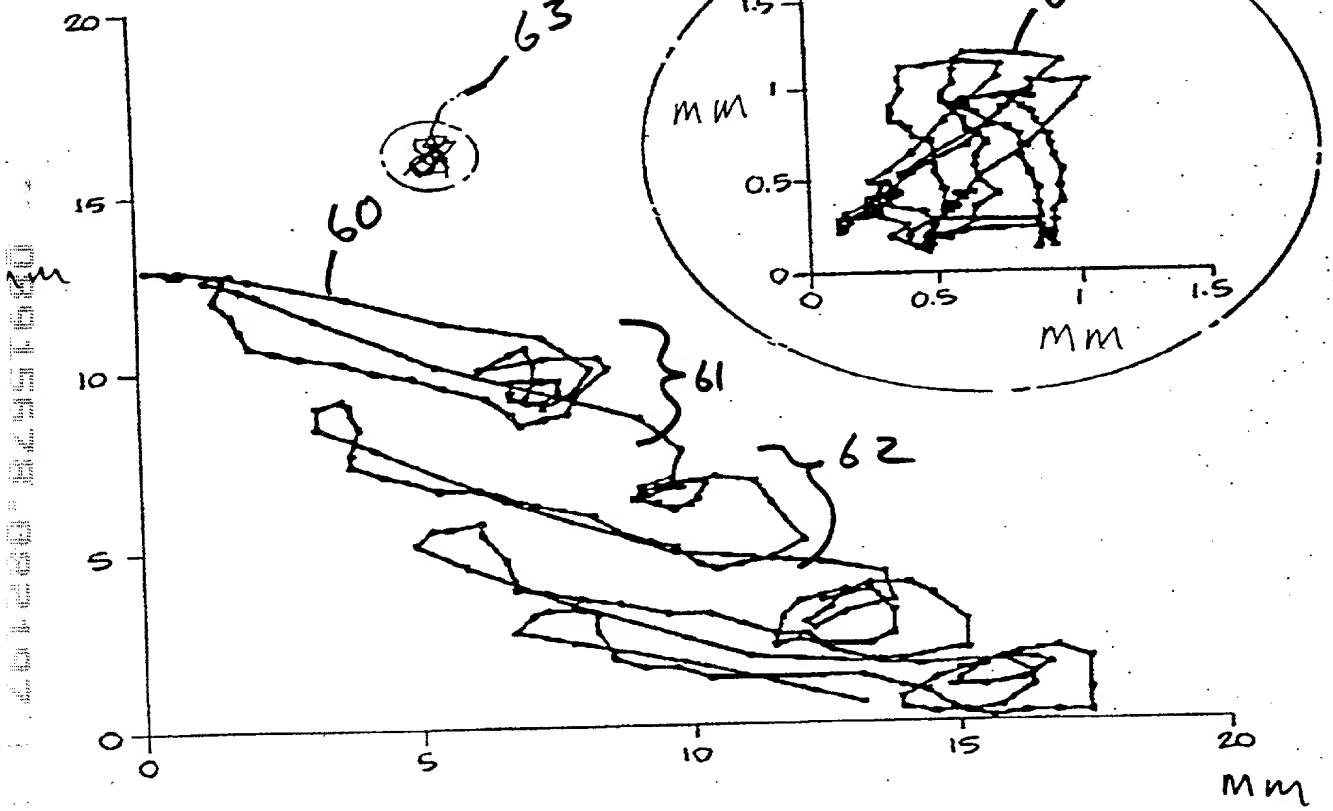


Fig. 12

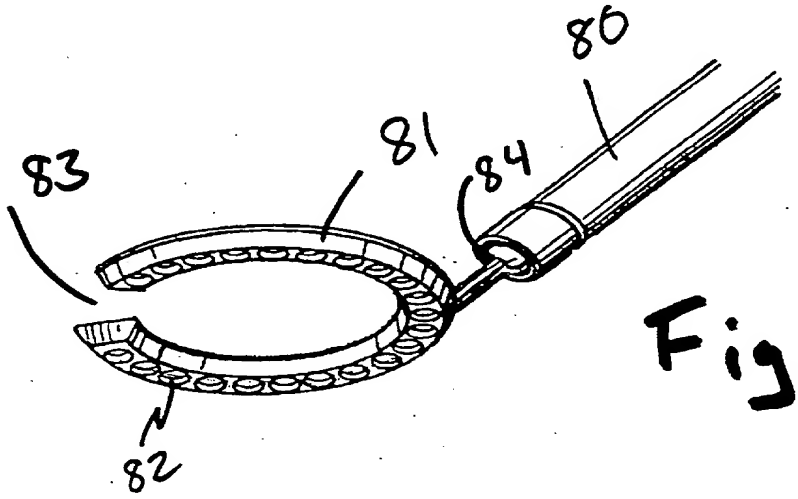
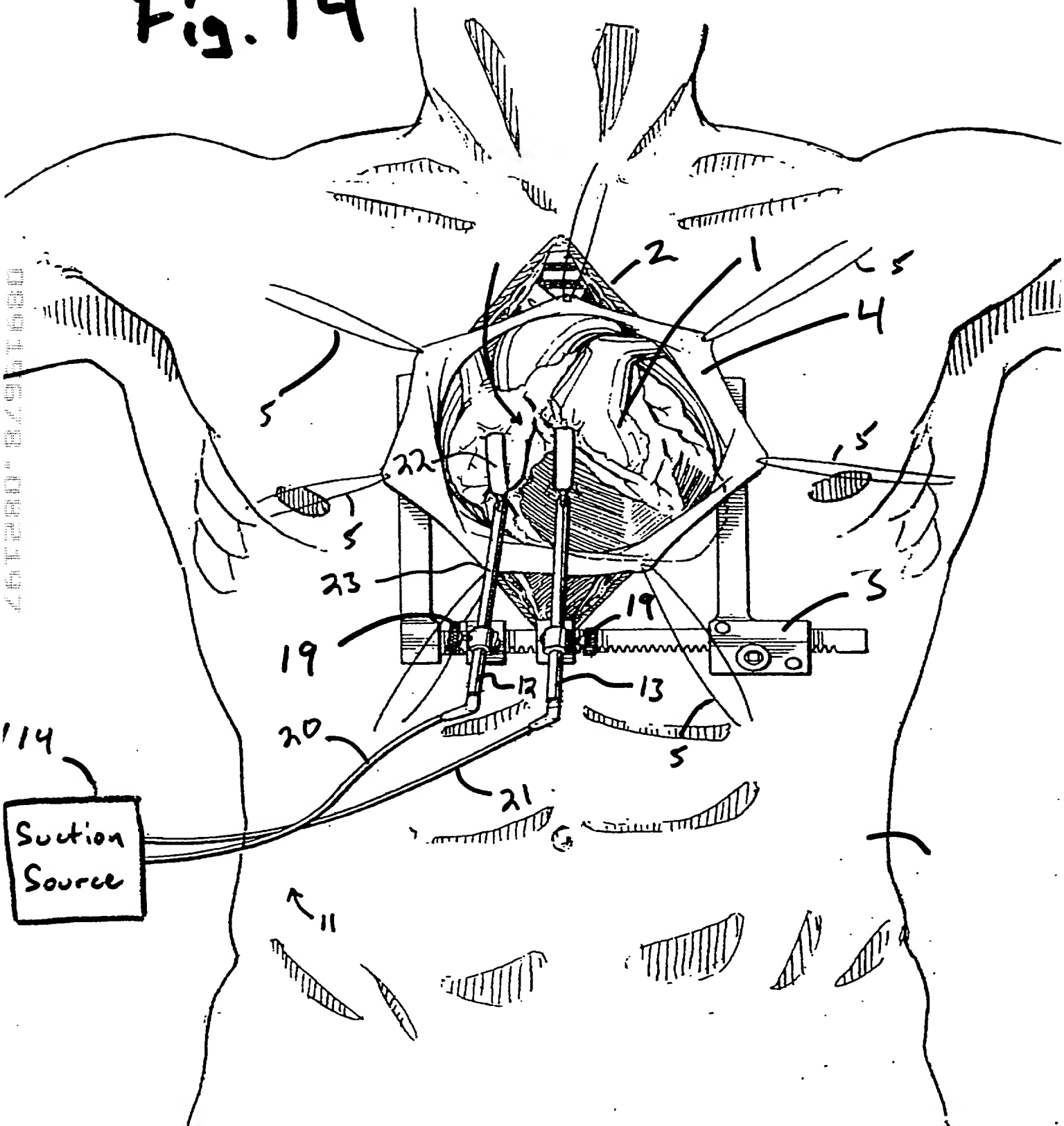


Fig. 13

Fig. 14



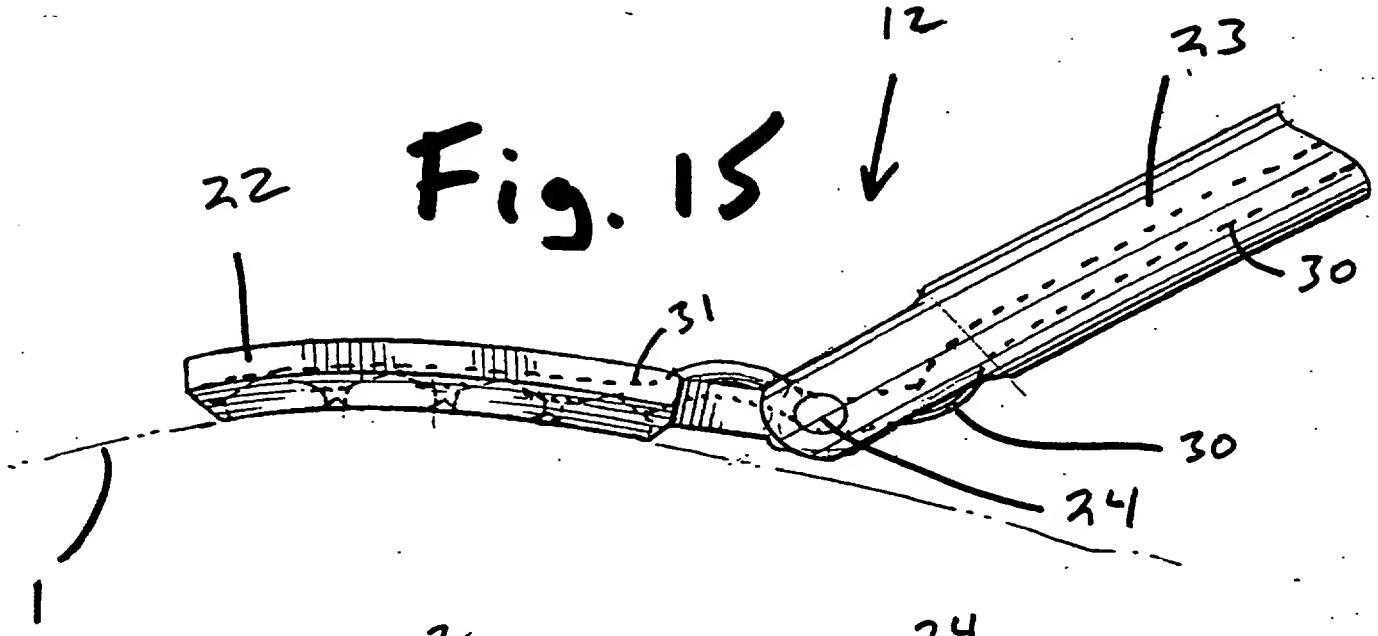


Fig. 15

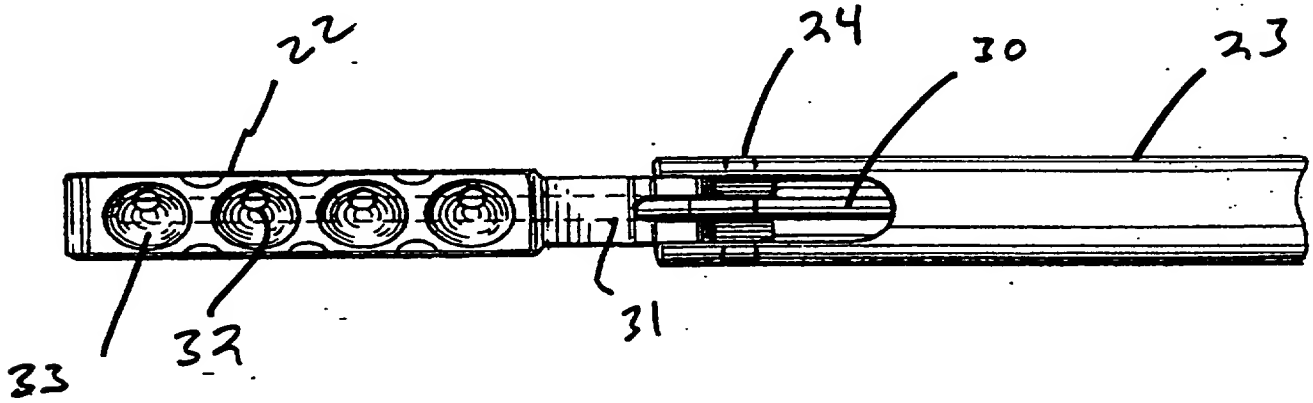


Fig. 16

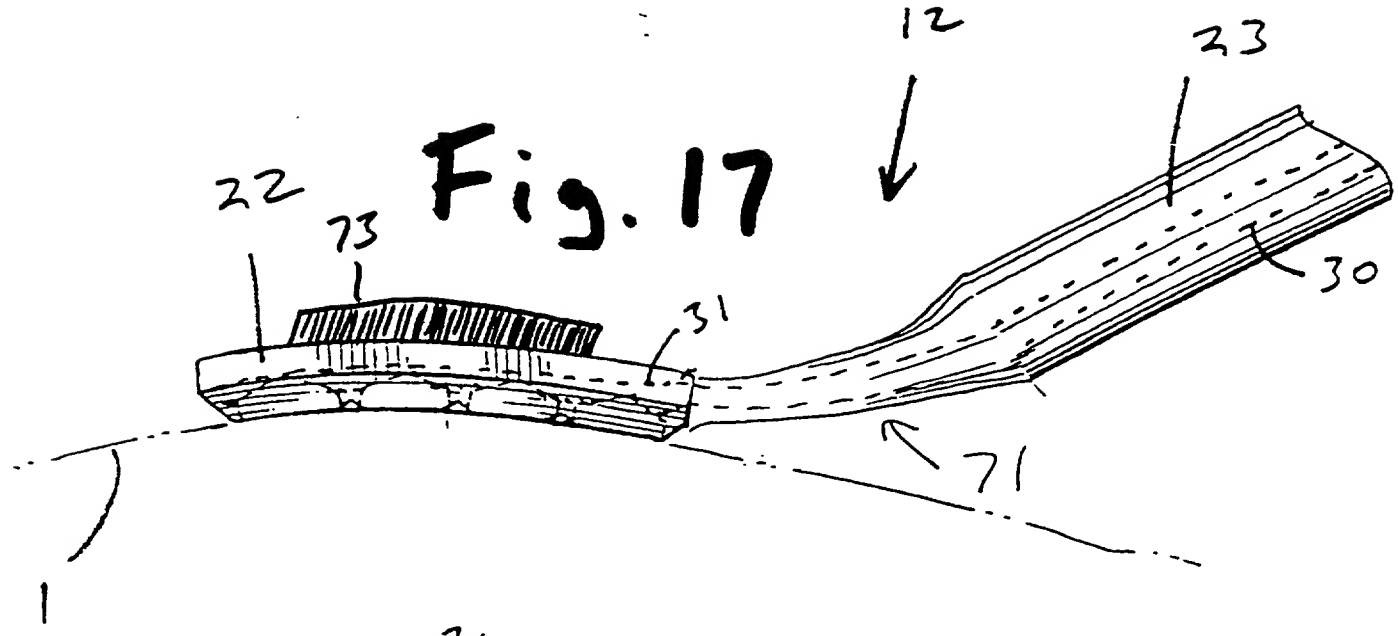


Fig. 17

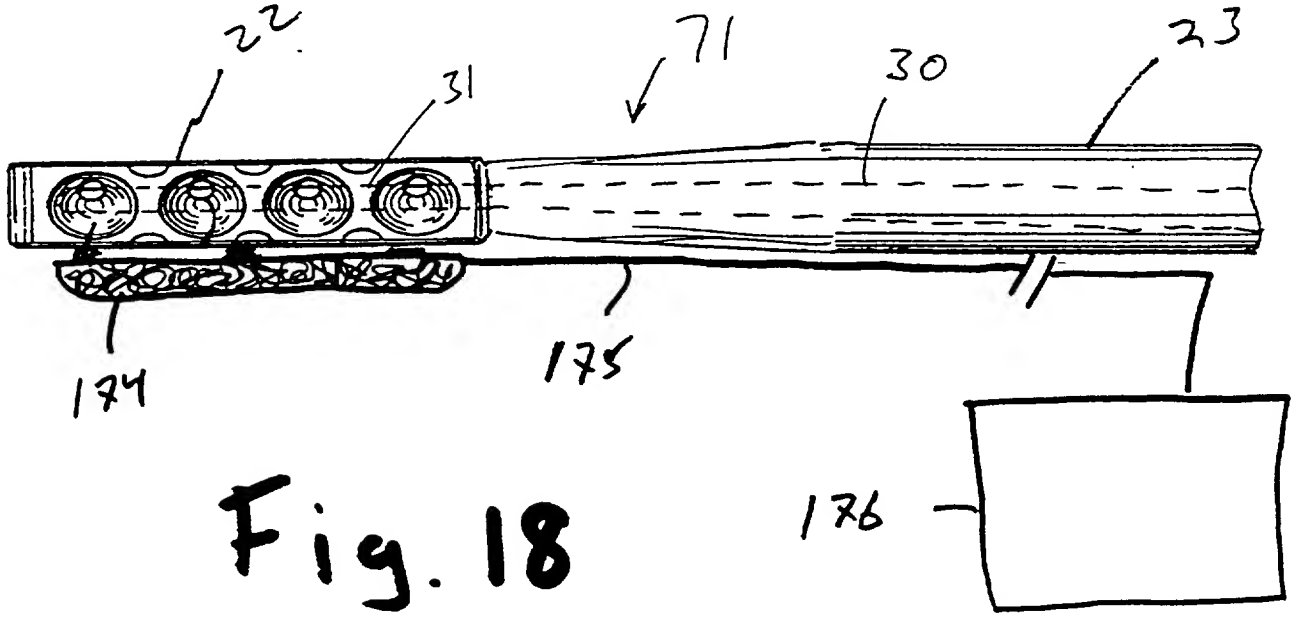


Fig. 18

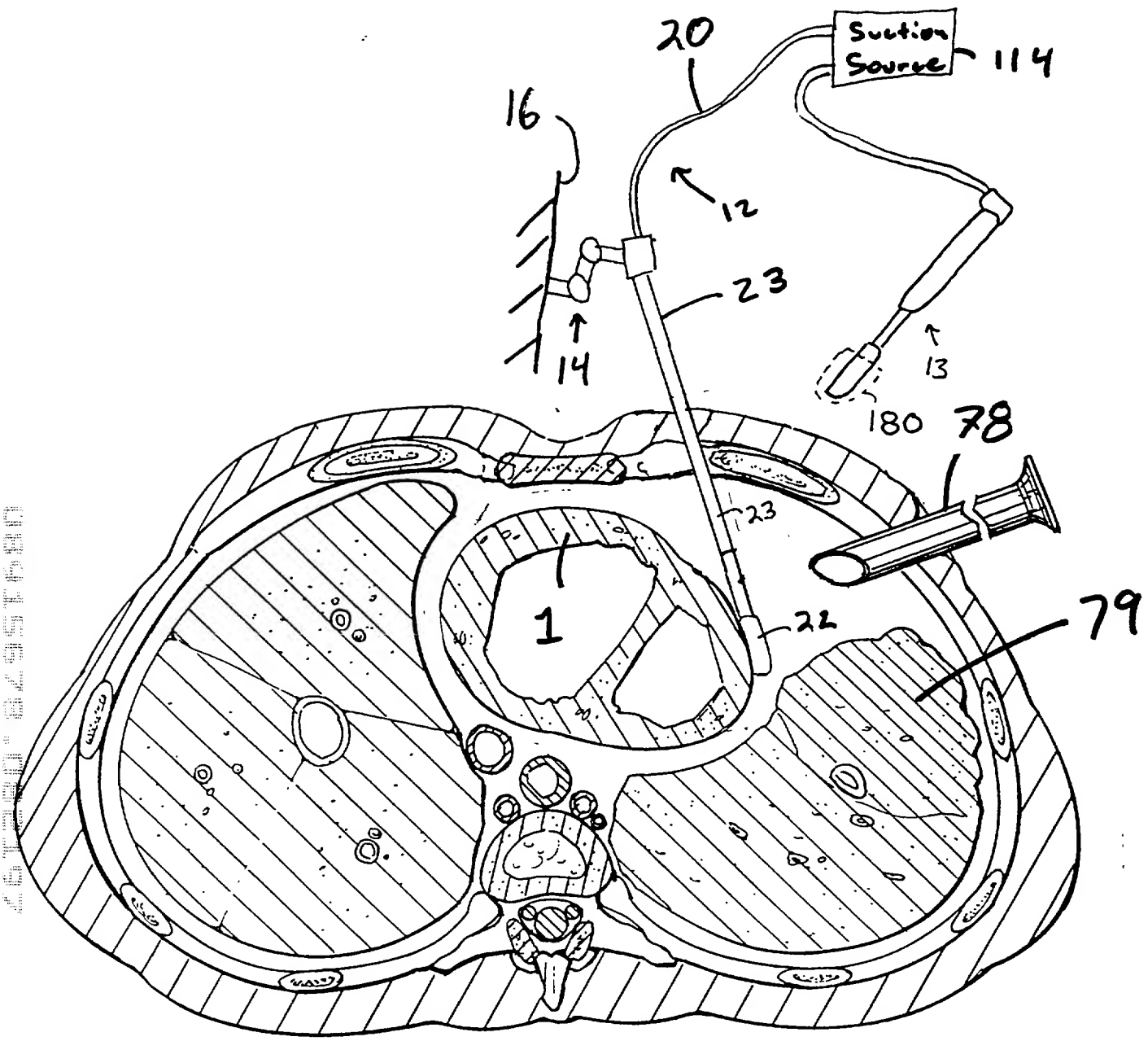


Fig. 19